DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

3 41220

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-36

June 23, 2003

Edwin J. Rincon, President
Indumar Seafood Corporation
1820 N. Corporate Lake Blvd., Suite 101
Weston, Florida 33326

Dear Mr. Rincon:

On April 10-15, 2003, the Food and Drug Administration, (FDA) conducted an inspection of your seafood import operation, located at the above address. The inspection was conducted to determine your firm's compliance with FDA's Seafood HACCP Regulations, 21 C.F.R. Part 123.

During our inspection, the FDA investigator observed shortcomings in your import verification procedures that appear to be deviations from the requirements of the Seafood HACCP Regulations. The investigator also provided you with a list of Inspectional Observations (Form FDA 483), which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations are as follows:

> You must have written product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 C.F.R. § 123.12(a)(2)(i). However, your firm has no written product specifications for cooked ready-to-eat crabmeat or for canned pasteurized crabmeat imported by your firm from [redacted]. This same deviation was previously brought to your attention in our letter of January 17, 2001.
>
> You must maintain records, in English, that document the performance and results of the affirmative steps your firm has implemented to comply with 21 C.F.R. § 123.12(c). However, the affirmative step records being maintained by your firm for cooked ready-to-eat crabmeat and canned pasteurized crabmeat imported by your firm from [redacted] in [redacted] are inadequate. The HACCP plan for cooked ready-to-eat crabmeat is missing the critical control point of cooking and fails to list a maximum critical limit for storage temperature. The HACCP plan for canned pasteurized crabmeat also fails to list a maximum critical limit for storage temperature. In addition, the HACCP plans are not completely written in English, signed or dated. A similar deviation was previously brought to your attention in our letter of January 17, 2001.

The deviations identified above are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products imported, processed and distributed by your firm are in compliance with the Food, Drug, and Cosmetic Act (the Act) and all requirements of the federal regulations.

These deviations cause your imported cooked ready-to-eat crabmeat and canned pasteurized crabmeat from [redacted] to be adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4). You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products imported by your facility.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these deviations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, you may contact Mr. Walthall by telephone at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District